

## **REMARKS**

Responsive to the official communication of March 31, 2004, Applicant submits the following Remarks.

### ***I. The Drawings***

The Office Action stated that Figures 1a-1d and 10a-10b were indecipherable. Formal replacement figures, including Figures 1a-1d and 10a-10b, in compliance with M.P.E.P § 608.02 have been submitted herewith.

### ***II. Information Disclosure Statement (IDS)***

The Office Action stated that no copies of the foreign references submitted with the IDS received by the Patent Office on January 29, 2002 (mailed by the Applicant on November 27, 2001) were received. Applicant has re-submitted the copies with a separate IDS mailed concurrently herewith. Per the Examiner, there will be no fee for the current submittal of the references.

### ***III. Double Patenting***

In the Office Action claims 1, 3-6, 9, 10, 12, 15, 18 and 19 are provisionally rejected for double patenting as being unpatentable over claims 1-3, 5, 6, 8, 12, 17-21, 25-27 of copending Application No. 09/943,647 ("the '647 application"). Applicant submits that the sets of claims are patentably distinct from each other for the following reasons. The present application concerns test members in sealed magazines which are slit when the magazine is pushed past a blade member, thereby enabling a pusher

to push a test member out through the slit. In the '647 application, a stack of test members in a housing is kept sealed behind a rotatable transport member which has an axis of rotation that spans an opening of the housing. The rotatable transport member has a recessed region adapted to receive a single test member from the stack. Rotation of the transport member with a test member in the recessed region transports the test member to a position where it engages with electrical contacts or to a position where it can be moved for such engagement. The claims of this application do not recite such a rotatable transport member. Furthermore, the claims of the '647 application do not recite the features of the blade means claimed in this application. The claims of this application recite a blade means in the housing for slitting the seal, wherein movement of the magazine from an initial position where the seal is intact, to a position where the pusher can push a test member from the stack thereby causing the blade means to cut the seal to form a slit through which a test member can pass when pushed by the pusher.

Accordingly, in view of the patentably distinct subject matter of the claims of the two applications, the double patenting rejection is improper and should be withdrawn.

#### ***IV. Claim Rejections – 35 USC § 102***

In the Office Action claims 1, 3, 4, 12, 13, and 15 are rejected as being anticipated under 35 U.S.C. § 102 by PCT Application WO 94/10558 by Friedlander et al (hereinafter Friedlander). The Applicant respectfully disagrees.

As acknowledged by the Examiner, Friedlander teaches an electrochemical sensor comprising a housing and a plurality of test elements arranged in a stack. The test elements are in a magazine 23 (page 4, 3rd full paragraph and Fig. 4) sealed by means of an O-ring 29 carried on the magazine. After a fluid sample has been applied to the top test element, the magazine is withdrawn against the pressure of a compression spring 26. An ejector 31 then displaces the spent element 28. Friedlander teaches away from the present invention, which requires blade means in the housing to make a slit in a moisture-impermeable seal on the magazine when the magazine is moved to a position where the pusher can dispense a test member. Friedlander does not disclose or suggest the provision of such blade means, and would not work with blade means because a blade could only function to cut the O-ring. However, cutting the O-ring would be contrary to the purpose and teaching of Friedlander, which is to maintain a sealed environment for those test members below the top member (which is open for a fluid sample 22 (Fig. 4a) .

In the present invention, the seal on the magazine is cut by blade means in the housing, as illustrated most clearly in Figure 3 and its accompanying description on page 9, lines 4-7. Advancement of the cartridge 12 moves the cartridge past the blade 22 which makes a slit in the seal at one end. This is in accordance with present claim 1, which requires that "wherein movement of the magazine relative to the housing from an initial position where the seal is intact to a position where the pusher can push a first test member from the stack thereby causing the blade means to cut the seal to form a slit through which a test member can pass when pushed by the pusher". These

features are not disclosed or suggested by any of the prior art documents of record, which are discussed briefly below.

As acknowledged by the Examiner, Friedlander describes a sensor stack held within a cartridge having a screw top sealed with an O-ring. This (the O-ring) provides airtight storage for the sensors when not in use. See page 5, 3<sup>rd</sup> full paragraph. Since the O-ring provides airtight storage for the sensors, Friedlander does not disclose a slit cut in a seal. Rather, Friedlander describes an airtight O-ring with no slit cut therein. Thus, the airtight seal of Friedlander is in direct contradiction to the claimed invention which requires a slit cut in a seal.

Because Friedlander fails to disclose a slit cut in a seal, the § 102 rejection of claim 1 is improper. Accordingly, the Applicant requests that the rejection of claim 1 and the claims dependent thereon, claims 3, 4, 12, 13, and 15 be withdrawn.

## **V. *Claim Rejections – 35 USC § 103***

***Because Friedlander Teaches Away From The Claimed Invention, Friedlander Cannot Be Used To Render The Claimed Invention Obvious.***

As set forth previously, Friedlander teaches away from the present invention, which requires a slit cut in a seal. Because Friedlander teaches away from the present invention, it is submitted that using Friedlander alone, or in combination, to render the claimed invention obvious is improper.

**Because Macindoe Fails To Teach Or Suggest The Claimed Blade, Friedlander And Macindoe Fail To Render The Claimed Invention Obvious.**

In the Office Action claims 2, 5-8, 14, and 16 were rejected as being obvious in view of Friedlander and U.S. Patent No. 5,460,778 issued to Macindoe. Macindoe relates to a complex automated analytical instrument. It includes a cutting assembly 171, the operation of which is described from column 11 line 54 to column 12 line 9. A rack and pinion arrangement drives block 211 (and hence, cutter element 221) horizontally towards a compartment 119 containing a desired assay module. This horizontal movement causes blade element 231 of cutter element 221 to sever three sides, for example the top, bottom and right side edges of the portion of the layer of material 127-1 covering compartment 119. Thus the blade element 231 is actively driven so as to cut three sides of the seal covering compartment 119. The mechanism then further pushes the now torn piece of the layer 127-1 into section 123 of compartment 119 before the cutting element 221 is retracted by the block 211. This mechanism is quite different from the present invention in which a blade in the housing cuts a slit in a magazine seal when the magazine moves from one position to another. As discussed above, one or ordinary skill in the art would have no motivation to combine the teachings of Friedlander and Macindoe because cutting the O-ring of Friedlander would be contrary to the purpose and teaching of Friedlander. Moreover, even if these teachings were to be combined, they would not result in the device specified in claim 1, in which movement of the magazine causes the blade to cut the seal.

Accordingly, it is requested that the rejection of claims 2, 5-8, 14, and 16, based on the proposed combination of Friedlander with Macindoe be withdrawn.

**Because Bottwein Fails To Teach Or Suggest The Claimed Blade, Friedlander And Bottwein Fail To Render The Claimed Invention Obvious.**

In the Office Action claims 11, 18, and 19 were rejected as being obvious in view of Friedlander and U.S. Patent No. 6,534,017 issued to Bottwein et al. Bottwein concerns a magazine for storing test elements. Bottwein neither discloses nor suggests use of a blade in a housing, to cut a seal on the magazine when the magazine is moved to a position where a pusher can push a test member therefrom. Accordingly, Applicant submits that present claim 1 would not be arrived at by any combination of Friedlander and Bottwein. Thus, it is respectfully requested that the rejections of claims 11, 18, and 19 based on the proposed combination of Friedlander and Bottwein be withdrawn.

**Because Jessop Fails To Teach Or Suggest The Claimed Blade, Friedlander And Jessop Fail To Render The Claimed Invention Obvious.**

In the Office Action claims 9 and 10 were rejected as being obvious in view of Friedlander and U.S. Patent No. 4,279,861 issued to Jessop be withdrawn. Jessop discloses apparatus for receiving a removable cartridge containing material for use in the apparatus, such as test elements for performing analyses of biological fluids. Jessop neither discloses nor suggests use of a blade in a housing, to cut a seal on the

magazine when the magazine is moved to a position where a pusher can push a test member therefrom. Accordingly, Applicant submits that present claim 1 would not be arrived at by any combination of Friedlander and Jessop.

Moreover, Jessop discloses use of a pawl and ratchet arrangement to prevent test elements accidentally being moved backwards into a magazine, but Jessop does not disclose the arrangement claimed in claim 9 in which the ratchet wheel has a keyway therein and the cartridge is provided with a plurality of spaced apart location pegs for locating in the keyway and the ratchet wheel only permitting entry of a location peg when the ratchet wheel is in a defined orientation.

Thus, it is respectfully requested that the rejection of claims 9 and 10 based on the proposed combination of Friedlander and Jessop be withdrawn.

#### **VI. Conclusion**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required beyond those, which may otherwise be provided for in documents accompanying this Amendment. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account 20-0823.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,



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